

Remarks

Claims 1-48 are pending. Claims 1-26 and 43-48 are withdrawn. Claims 27-42 are rejected.

Information Disclosure Statement

The Examiner alleged that the lined-through references listed in the returned Form 1449 submitted on November 12, 2003 lack proper citation. Applicants respectfully submit that Applicants have substantially complied with the requirement as set forth in 37 CFR 1.98(b)(5) because these references are online publications, the publication dates of which are essentially impossible to ascertain. Applicants respectfully request that these references be examined.

Rejections under 35 U.S.C. 112, first paragraph

Claims 34 and 39 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants believe the amendments to claims 34 and 39 cure the alleged deficiencies.

Rejections under 35 U.S.C. 112, second paragraph

Claims 27-42 are rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite. Applicants believe the rejections of claims 27-42 for reciting the term “less than about” and the term the “including” are moot in light of the amendment to the claims.

With respect to the recitation of the term “substantially” in claims 33-35, Applicants respectfully direct the Examiner to MPEP §2173.05(c)(D), which indicates that the Courts repeated held that the term “substantially” recited in a claim **is definite**

and can be construed according to the generally guidelines as provided in the specification.

Rejections under 35 U.S.C. 102

Claims 27-30 and 33-36 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,837,313 to Ding et al. ("Ding").

Claim 27 defines a method of manufacturing a drug delivery implantable medical device. The method includes (a) applying a composition to an implantable medical device, the composition comprising a polymer, an active agent and a solvent; (b) allowing the solvent to evaporate to form a dry coating, the dry coating comprising less than 10% residual fluid content (w/w); and (c) directing a beam of charged particles to the dry polymeric coating to modify the release rate of the active agent from the coating.

The beam of charged particles has a current density from about 0.001 $\mu\text{A}/\text{cm}^2$ to about 1 $\mu\text{A}/\text{cm}^2$. As described in the specification, **the recited range of current density allows the claimed method to modify the release rate of the active agent from the coating without producing a temperature that significantly degrades the active agent disposed in the coating or adversely affects the polymer in the coating.**

Ding describes a method of coating a stent with a step of plasma treatment. The coating can include a polymeric silicone material. However, Ding does not describe or teach treating the coating described therein with a beam of charged particles to the dry polymeric coating to **modify the release rate of the active agent from the coating, the beam of charged particles having a current density from about 0.001 $\mu\text{A}/\text{cm}^2$ to about 1 $\mu\text{A}/\text{cm}^2$.** Accordingly, claim 27 is patentably allowable over Ding under 35 U.S.C. 102(b). Claims 28-30 and 33-36 depend from claim 27 and are patentably

allowable over Ding under 35 U.S.C. 102(b) for at least the same reason.

Claims 27-29 and 33-36 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,713,119 to Hossainy et al. ("Hossainy").

Claim 27 is discussed above. Hossainy describes a method of forming a coating on a prosthesis comprising a polymer. Hossainy also describes that coating can be subjected to sterilization by "electron beam radiation". However, Hossainy does not describe or teach treating the coating described therein with a beam of charged particles to the dry polymeric coating to **modify the release rate of the active agent from the coating, the beam of charged particles having a current density from about 0.001 $\mu\text{A}/\text{cm}^2$ to about 1 $\mu\text{A}/\text{cm}^2$** . Accordingly, claim 27 is patentably allowable over Hossainy under 35 U.S.C. 102(b). Claims 28, 29 and 33-36 depend from claim 27 and are patentably allowable over Hossainy under 35 U.S.C. 102(b) for at least the same reason.

Rejections under 35 U.S.C. 103

Claims 27-30, 33-36, 39 and 41 are rejected as being obvious over Ding in view of U.S. Patent No. 6,120,847 to Yang et al. ("Yang") under 35 U.S.C. 103(a).

As discussed above, Ding fails to describe or teach **a beam of charged particles having a current density from about 0.001 $\mu\text{A}/\text{cm}^2$ to about 1 $\mu\text{A}/\text{cm}^2$** . Yang describes a method of eliminating polymeric fibers, polymeric particles or polymeric surface aberrations or imperfections from a polymeric coating on a medical device. The method includes contacting a polymeric coating with the above surface aberrations or imperfections with a vaporized solvent. Yang does not describe or teach the element of **"a beam of charged particles having a current density from about 0.001 $\mu\text{A}/\text{cm}^2$ to**

about 1 $\mu\text{A}/\text{cm}^2$.” Therefore, Ding and Yang, individually or combined, does not describe or teach the element of “a beam of charged particles having a current density from about 0.001 $\mu\text{A}/\text{cm}^2$ to about 1 $\mu\text{A}/\text{cm}^2$.” Accordingly, claim 27 is patentably allowable over Ding and Yang, individually or combined, under 35 U.S.C. 103(a). Claims 28-30, 33-36, 39 and 41 depend from claim 27 and are patentably allowable over Ding and Yang, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

Claims 27-30, and 32 are rejected as being obvious over U.S. Patent No. 5,464,650 to Berg et al. (“Berg”) in view of Han et al., Journal of the Electrochemical Society 146(11):4327-4333 (1999) (“Han”) under 35 U.S.C. 103(a).

Berg describes a method of forming a coating on a stent, the coating including a polymer and a drug. As the Examiner correctly notes, Berg does not describe or teach directing a beam of charged particles to the coating described therein.

Han describes a method of modifying the surface of chemically resistive tubes, vessels and container walls to improve wetting, dye printing and adhesion to another phase, which are industry articles entirely different or irrelevant to modifying the release rate of a drug from a coating on an implantable medical device, which is for use in a human being. As such, Berg and Han are not combinable (see, MPEP §§2143 and 2145). Further, because Han does not describe or teach modifying a coating on the implantable medical device, Han cannot provide motivation for an ordinary skill in the art to modify Berg using a beam of charged particles to the coating described in Berg. Therefore, by combining Berg and Han to reject the claims, the Examiner uses impermissible hindsight (see, MPEP §2145).

Even if Berg and Han were combinable, Berg and Han would still fail to provide for **“a beam of charged particles having a current density from about 0.001 $\mu\text{A}/\text{cm}^2$ to about 1 $\mu\text{A}/\text{cm}^2$ ”** as recited in claim 27.

In sum, claim 27 is patentably allowable over Berg and Han, individually or combined, under 35 U.S.C. 103(a). Claims 28-30 and 32 depend from claim 27 and are patentably allowable over Berg and Han, individually or combined, under 35 U.S.C. 103(a) for at least the same reason.

Claims 33-35 are rejected as being obvious over Berg and Han further in view of U.S. Patent No. 5,624,411 to Tuch et al. (“Tuch”).

Claims 33-35 depend from claim 27, which requires modifying a coating to modify the release of an agent by directing **“a beam of charged particles having a current density from about 0.001 $\mu\text{A}/\text{cm}^2$ to about 1 $\mu\text{A}/\text{cm}^2$ ”**.

Berg and Han are discussed above. Tuch describes a method of forming a coating that includes a porous polymer and a drug. **Tuch does not describe modifying the release rate of the drug by directing a beam of charged particles to the coating to modify, the beam having a current density from about 0.001 $\mu\text{A}/\text{cm}^2$ to about 1 $\mu\text{A}/\text{cm}^2$** . Therefore, Tuch does not cure the deficiencies of Berg and Han. Therefore, claims 33-35 are patentably allowable over Berg and Han in view of Tuch under 35 U.S.C. 103(a).

Claims 37 and 38 are rejected as being obvious over Berg and Han further in view of EP 0970711 (“EP 711”).

Claims 37 and 38 depend from claim 27 and require modifying a coating to modify the release rate of an agent by directing “a beam of charged particles having a

current density from about $0.001 \mu\text{A}/\text{cm}^2$ to about $1 \mu\text{A}/\text{cm}^2$." As discussed above, Berg and Han do not provide this element. EP 711 describes a method of forming a coating on a stent having a first and second surface with passages therebetween. EP 711 does not describe or teach modifying the release rate of an agent by directing "a beam of charged particles having a current density from about $0.001 \mu\text{A}/\text{cm}^2$ to about $1 \mu\text{A}/\text{cm}^2$."

Therefore, EP 711 does not cure the deficiencies of Berg and Han. As such, claims 37 and 38 are patentably allowable over Berg and Han in view of EP 711 under 35 U.S.C. 103(a).

The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

CONCLUSIONS


Withdrawal of the rejection and allowance of the claims are respectfully requested.

If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the undersigned attorney for approval of an Examiner's amendment. If the Examiner

has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9885.

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Respectfully submitted,



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